



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 6, 2019

Sara Selter  
Registration Specialist  
Diversey, Inc.  
P.O Box 19747  
Charlotte, NC 28219-0747

Subject: PRIA Label Amendment – Adding Efficacy Claims and Emerging Viral Pathogens Language  
Product Name: Oxivir Tb  
EPA Registration Number: 70627-56  
Application Date: January 29, 2019  
Decision Number: 551692

Dear Ms. Selter:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is: small non-enveloped, large non-enveloped, enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Piconavirus and Canine Parvovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at [johnson.zebora@epa.gov](mailto:johnson.zebora@epa.gov).

Sincerely,



Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped Label

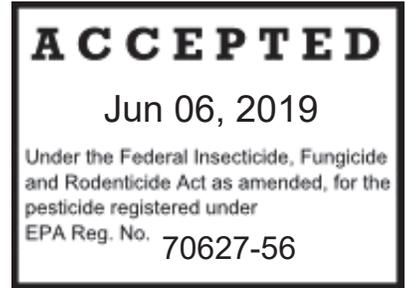
(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

# OXIVIR Tb

(Ready to Use)  
(One-Step Disinfectant) (and) (Deodorizer)  
(General) (\*Virucide), (Bactericide), (Tuberculocide), (Fungicide), (Sanitizer)  
(Cleaner) (Disinfectant) (Deodorizer)  
(Cleaner spot sanitizer on soft surfaces<sup>†</sup>)

(Hydrogen Peroxide)

For (Industrial) (&) (Institutional) Use



<b>ACTIVE INGREDIENT:</b>	
Hydrogen Peroxide .....	0.5%
<b>OTHER (INERT) INGREDIENTS:</b> .....	99.5%
<b>TOTAL:</b> .....	100.0%

## KEEP OUT OF REACH OF CHILDREN CAUTION

(See additional precautionary statements on (back) (side) (left) (right) (panel) (label) (below).)

(See reference sheet (enclosed in each case) for (a complete list of organisms) (additional (features) (claims) (directions for use)) (for this product).)

Net Contents:

(Product of XXXXXXXXX)

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

## **(FEATURES, CLAIMS & USES:)**

### **(General Uses:)**

For Use in Health Care, Veterinary, Animal Housing, Dental, (Life Science) Laboratory, Medical, Industrial & Institutional Facilities, Food Processing Establishments, and Hospitals.

This product is a one-step (hospital-use) germicidal disinfectant and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting (deodorizing) (of) hard, non-porous inanimate surfaces. It cleans by removing dirt, grime, and other common soils found in *[insert use sites/surfaces from lists below]* (or –hard, non-porous washable surface where disinfection is required.)

It is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces): *-[insert use sites/surfaces from lists below]* – (where disinfection is required). A potable water rinse is required for food contact surfaces. Do not use on glasses, dishes and utensils.

### **(Soft Surface Spot Sanitization:)**

- A proven spot sanitizer on soft surfaces<sup>†</sup>
- An effective soft surface<sup>†</sup> spot sanitizer
- Spot sanitizes soft surfaces<sup>†</sup> in 30 seconds

(Great) For use as a spot sanitizer on soft surfaces<sup>†</sup> (composed of cotton or polyester). (This product) Kills (removes) (sanitizes) microorganisms on soft surfaces<sup>†</sup> or fabric<sup>†</sup> including: blinds, bedding, blankets, chairs, couches, curtains, drapes, exercise mats, gym bags, headrests, linens, mats, mattresses, seat (soft) cushions, shades, sheets, sofas, sports equipment (lining), towels, upholstered furniture, upholstery, washcloths, and window treatments. Removes (and) (or) (eliminates) odors by killing odor-causing bacteria on soft surfaces<sup>†</sup> or fabrics<sup>†</sup>.

[Note: Prior to first use on a particular surface, it is recommended to test in a small, discreet area if there is concern of incompatibility.]

<sup>†</sup>plain cotton weave and 100% polyester fabric

(This product) (Oxivir Tb) *[insert marketed product name]* cleans and disinfects *[insert organism name(s) from list in Efficacy Claims section]* including ESKAPE pathogens - *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumonia, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter aerogenes*

(This product) (Oxivir Tb) *[insert marketed product name]* kills ESKAPE organisms with a 1 minute kill time.

(This product) (Oxivir Tb) *[insert marketed product name]* cleans and disinfects, killing ESKAPE organisms with a 1-minute dwell time.

Kills ESKAPE bacteria in 1 minute

### **(Hospitals/Health Care Facilities/Dental Offices/Life Science Laboratories:)**

This product is a one-step (hospital-use) (laboratory-use) germicidal disinfectant and deodorant (odor-counteractant) (odor neutralizer) designed for general cleaning, (and) disinfecting, (deodorizing) (of) hard, non-porous inanimate surfaces. This product cleans by removing dirt, grime, food residue, dead skin, blood and other organic matter commonly found in *[insert use sites/surfaces from lists below]*. It also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

This product cleans, disinfects and deodorizes hard, non-porous inanimate (hospital) (medical) (dental) (laboratory) surfaces in one step (with no rinsing required). Its non-abrasive formula is designed for use on (Use daily on) (the following) (hard, non-porous inanimate surfaces:)-*[insert use sites/surfaces from lists below]* (or –hard, non-porous

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

washable surface where disinfection is required.) found in *[insert use sites/surfaces from lists below]* (It can be used to pre-clean and disinfect hospital items: *[insert use sites/surfaces from lists below]* – (where disinfection is required). A potable water rinse is required when disinfecting food contact surfaces. Do not use on glasses, dishes and utensils.

**(Animal Housing Facilities:)**

This product cleans by removing dirt, grime, blood, urine, fecal matter and other common soils found in animal housing facilities, grooming facilities, farms, kennels, pet stores, veterinary clinics, laboratories or other small animal facilities. It (also) eliminates odors leaving surfaces smelling clean and fresh.

This product cleans, disinfects and deodorizes hard, non-porous environmental surfaces in one step. Its non-abrasive formula is designed for use on (Use daily on) (Use daily to clean and disinfect) (hard, non-porous surfaces:) *[insert use sites/surfaces from lists below]* (where disinfection is required.) found in (barns, pens and stalls) animal housing facilities.

**(USE SITES:)**

(Oxivir Tb) (This product) can be used (in) (on) hard non-porous surfaces of the following items or in the following areas:

**(Medical Facilities/Hospitals/Health Care Facilities/Dental Offices/Life Science Laboratories :)**

<ul style="list-style-type: none"> <li>• alternative care facilities,</li> <li>• ambulances or (emergency medical) transport vehicles,</li> <li>• ambulatory care centers (ASCs); ambulatory surgery centers,</li> <li>• anesthesia rooms,</li> <li>• assisted living facilities,</li> <li>• (acute) (and) (long-term) care facilities,</li> <li>• backboards,</li> <li>• (hospital) (patient) bedrails and linings (patient bed linings), (vinyl mattress covers),</li> <li>• bedpans,</li> <li>• (hospital) (patient) bedrails, bedframes, bed springs, side rails,</li> <li>• bedside (overbed) table,</li> <li>• (bedside) commodes,</li> <li>• blood pressure cuffs (for use on hard, non-porous surfaces)</li> <li>• blood pressure monitors,</li> <li>• CAT laboratories,</li> <li>• (crash) (medication) carts,</li> <li>• cabinets,</li> <li>• (nurse) call buttons (boxes) (devices),</li> <li>• central service areas,</li> <li>• central supply rooms,</li> <li>• clinics,</li> </ul>	<ul style="list-style-type: none"> <li>• diagnostic equipment,</li> <li>• dialysis clinics (facilities),</li> <li>• (blood) (plasma) donation centers,</li> <li>• examination (exam) rooms (areas),</li> <li>• exam tables</li> <li>• emergency rooms (ERs) (areas),</li> <li>• eye surgical centers,</li> <li>• footboards,</li> <li>• gurneys,</li> <li>• health care facilities,</li> <li>• hospices,</li> <li>• hospitals,</li> <li>• infant incubators,</li> <li>• instrument trays,</li> <li>• IV stands (poles) and exterior surfaces of pumps,</li> <li>• (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs) (areas),</li> <li>• isolation rooms (areas),</li> <li>• laboratories,</li> <li>• laboratory settings</li> <li>• laundry rooms,</li> <li>• long-term care facilities (homes),</li> <li>• (medical assistance services),</li> <li>• medical facilities,</li> </ul>	<ul style="list-style-type: none"> <li>• (neonatal) (newborn) nurseries,</li> <li>• nursing homes,</li> <li>• nurses stations,</li> <li>• operating rooms (theaters),</li> <li>• ophthalmic offices,</li> <li>• outpatient (surgical) centers (clinics) (OPSCs) (facilities),</li> <li>• paddles,</li> <li>• patient rooms (areas),</li> <li>• patient care (monitoring) equipment,</li> <li>• pharmacies,</li> <li>• phlebotomy trays,</li> <li>• (physical) (patient) therapy rooms,</li> <li>• physical therapy equipment,</li> <li>• procedure rooms,</li> <li>• psychiatric facilities,</li> <li>• radiology (X-Ray) rooms (areas),</li> <li>• reception areas,</li> <li>• recovery rooms,</li> <li>• rehabilitation centers,</li> <li>• respiratory therapy rooms,</li> <li>• skilled nursing facilities,</li> <li>• stethoscopes,</li> <li>• stretchers,</li> <li>• surgery rooms,</li> <li>• traction bars, devices and patient slings,</li> <li>• waiting rooms (areas)</li> <li>• wash basins,</li> </ul>
---	--	---

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

<ul style="list-style-type: none"> <li>critical care units,</li> <li>dental chairs,</li> <li>dental clinics,</li> <li>dental curing lights,</li> <li>dental offices,</li> <li>dental operatory surfaces,</li> </ul>	<ul style="list-style-type: none"> <li>(medical) (physicians') (doctors') offices,</li> </ul>	<ul style="list-style-type: none"> <li>wheelchairs,</li> <li>x-ray equipment,</li> </ul>
---	---	--

**(USE SITES, continued)**

(Oxivir Tb) (This product) can be used (in) (on) hard non-porous surfaces in the following areas:

**(Animal/Veterinary Facilities/Animal Housing Facilities:)**

<ul style="list-style-type: none"> <li>animal equipment,</li> <li>animal crates,</li> <li>animal hospitals,</li> <li>animal housing facilities,</li> <li>animal treatment facilities,</li> <li>animal life science laboratories,</li> <li>automatic feeders not for food contact,</li> <li>barns, pens, and stalls,</li> <li>bathrooms,</li> <li>brushes,</li> <li>buckets,</li> <li>bus (depots) (stations),</li> <li>cages,</li> <li>carts,</li> <li>non food contact counters,</li> </ul>	<ul style="list-style-type: none"> <li>crates,</li> <li>dog runs,</li> <li>examination tables</li> <li>exercise facilities,</li> <li>exercise equipment,</li> <li>farm vehicles (trucks),</li> <li>fencing,</li> <li>fume hoods and animal cages (found in laboratory settings),</li> <li>farms,</li> <li>gates,</li> <li>gathering (guiding) equipment,</li> <li>general merchandise stores,</li> <li>grooming equipment,</li> <li>grooming facilities,</li> </ul>	<ul style="list-style-type: none"> <li>health clubs,</li> <li>handling equipment,</li> <li>harnesses &amp; leashes,</li> <li>kennels,</li> <li>kennel runs,</li> <li>laboratories or other small animal facilities,</li> <li>office buildings,</li> <li>pens,</li> <li>pet shops (equine farms),</li> <li>shower rooms (areas),</li> <li>troughs,</li> <li>veterinary clinics</li> <li>veterinary equipment,</li> <li>veterinary care surfaces,</li> <li>(wash) stalls,</li> </ul>
--	---	--

**(General Areas:)**

<ul style="list-style-type: none"> <li>Airplanes,</li> <li>airports,</li> <li>aluminum</li> <li>athletic equipment,</li> <li>athletic facilities,</li> <li>baked enamel surfaces associated with floors,</li> <li>barber/beauty (salons) (shops),</li> <li>exterior surfaces of air vents covers,</li> <li>cabinets,</li> <li>cages,</li> <li>carts,</li> <li>casinos,</li> <li>ceilings</li> <li>chairs ,</li> <li>changing tables,</li> <li>chrome</li> <li>closets,</li> <li>coated (removable) (plastic)</li> </ul>	<ul style="list-style-type: none"> <li>convention centers,</li> <li>correctional facilities,</li> <li>counters † ,</li> <li>cruise ships,</li> <li>day care centers † ,</li> <li>desks, ‡</li> <li>desktops ,</li> <li>docking stations, ‡</li> <li>doors ,</li> <li>drawers,</li> <li>elevators,</li> <li>exercise equipment,</li> <li>exercise facilities,</li> <li>faucets,</li> <li>fixtures,</li> <li>floors (flooring),</li> <li>funeral homes,</li> <li>glass,</li> <li>glazed ceramic,</li> <li>glazed ceramic (restroom)</li> </ul>	<ul style="list-style-type: none"> <li>hand rails (railings),</li> <li>hotels (motels),</li> <li>institutions,</li> <li>laminated surfaces</li> <li>laptops,</li> <li>laundromats,</li> <li>libraries,</li> <li>light fixtures, switches,</li> <li>lockers,</li> <li>locker rooms (areas),</li> <li>lounges,</li> <li>mirrors,</li> <li>military installations,</li> <li>mobile devices (electronic equipment),</li> <li>mobile workstations,</li> <li>Naugahyde,</li> <li>train (depots) (stations),</li> <li>transportation terminals (facilities),</li> <li>tables,</li> </ul>
---	--	---

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

<ul style="list-style-type: none"> <li>covers for mattresses and pillows,</li> <li>• computer mouse, keyboards, peripherals, screens, tables,</li> <li>• convenience stores,</li> <li>• non-food contact countertops,</li> <li>• non-food contact surfaces,</li> <li>• office buildings</li> <li>• pagers,</li> <li>• painted surfaces,</li> <li>• phones, phone cradles and accessories,</li> <li>• plastic (surfaces),</li> <li>• plated steel</li> <li>• playgrounds,</li> <li>• public buildings,</li> <li>• public restrooms,</li> <li>• recreational facilities,</li> <li>• restrooms,</li> <li>• rest stops (public restrooms),</li> <li>• retail businesses</li> </ul>	<ul style="list-style-type: none"> <li>tile,</li> <li>• glazed porcelain,</li> <li>• glazed tile,</li> <li>• handheld electronic devices,</li> <li>• schools (colleges, and universities),</li> <li>• shelves,</li> <li>• shopping centers,</li> <li>• showers,</li> <li>• shower fixtures,</li> <li>• shower rooms (areas)</li> <li>• sinks,</li> <li>• sink basins,</li> <li>• sinks found in (health care facilities),</li> <li>• (hospitals), (dental offices), (patient rooms), (operating rooms), (ICU areas), (shower rooms), and (locker rooms)</li> <li>• stainless steel,</li> <li>• stools,</li> <li>• spas,</li> <li>• sports arenas (stadiums)</li> </ul>	<ul style="list-style-type: none"> <li>• tablet PCs,</li> <li>• telephones,</li> <li>• tubs,</li> <li>• exterior surfaces of toilets,</li> <li>• toilet exteriors,</li> <li>• toilets</li> <li>• exterior surfaces of urinals,</li> <li>• urinal exteriors,</li> <li>• urinals,</li> <li>• walls,</li> <li>• wash basins,</li> <li>• vinyl</li> </ul>
--	--	---

†Non-Food Contact Surfaces

\*Except Wood Surfaces

**(Refill)**

To Transfer This Product Into Smaller Containers:

[This product may be transferred into clean, properly labeled containers for use elsewhere within your facility.] The small container and transfer items (funnels or hand pumps) must be clean and dry. Pour (or pump) product directly into a properly labeled smaller container being careful not to spill any product. Keep containers sealed when not in use. Refill in a well ventilated area.

**DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

*(Note to Reviewer: For labels that list medical devices as defined by the FDA.)*

(This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

**(CLAIMS:)**

When used as directed, this product is effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, *[list of antibiotic resistant organisms is below, in Efficacy Claims section, under subheading Antibiotic-Resistant (Strains of) Bacteria]*, viruses, and fungi). (See reference sheet (enclosed in each case) for a complete list of organisms.)

**(HOSPITAL DISINFECTANT:)**

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

**BACTERICIDAL:**

[Note to reviewer: Only one of the following statements will be on the product label]

(in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(1 minute contact time)

- or -

(1 minute)

**(Bactericidal Activity):**

(Organism)	(ATCC Number)	(Contact Time)
<i>Staphylococcus aureus</i>	(ATCC 6538)	1 minute
<i>Pseudomonas aeruginosa</i>	(ATCC 15442)	1 minute
<i>Salmonella enterica</i> , formerly known as <i>Salmonella choleraesuis</i>	(ATCC 10708)	1 minute
<i>Acinetobacter baumannii</i>	(ATCC 19606)	1 minute
<i>Escherichia coli</i> O157:H7	(ATCC 35150)	1 minute
<i>Klebsiella pneumonia</i>	(ATCC 4352)	1 minute
<i>Shigella dysenteriae</i>	(ATCC 11835)	1 minute

**(Antibiotic-Resistant (Strains of) Bacteria [list below]):**

<i>Enterococcus faecalis</i> (Resistant to Vancomycin (VRE))	(ATCC 51575)	1 minute
<i>Escherichia coli</i> with extended beta-lactamase resistance (ESBL), (ATCC BAA-196)	(ATCC BAA-196)	1 minute
<i>Staphylococcus aureus</i> (Resistant to Methicillin (MRSA))	(ATCC 33592)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant)	(NARSA NRS 384)(Genotype USA300)	1 minute
<i>Staphylococcus aureus</i> (CA-MRSA), (Community Associated Methicillin Resistant)	(NARSA NRS 123)(Genotype USA400)	1 minute

**VIRUCIDAL:**

[Note to reviewer: Only one of the following statements will be on the product label]

(in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)

- or -

(1 minute contact time)

- or -

(1 minute)

**(Viruses (Virucidal Activity)):**

(Organism)	(ATCC Number)	(Contact Time)
Adenovirus type 8	(ATCC VR-1368)	1 minute
Hepatitis B Virus (HBV)	(Acquired from Hepadnavirus Testing)	1 minute
Hepatitis C Virus (HCV)	(Acquired from National Veterinary Services Laboratories)	1 minute
Herpes Simplex Virus, Type 1 (HSV-1)	(ATCC VR-733)	1 minute
Herpes Simplex Virus, Type 2 (HSV-2)	(ATCC VR-734)	1 minute
HIV-1 (AIDS Virus), Strain HTLV-III <sub>B</sub> (HIV-1)	(Acquired from Adv. Biotechnologies, Inc.)	1 minute
Human Coronavirus, (ATCC VR-740)	(ATCC VR-740)	1 minute
Influenza A/Hong Kong, (ATCC VR-544)	(ATCC VR-544)	1 minute
Norovirus, (Feline Calicivirus as the surrogate)	(Feline Calicivirus, ATCC VR-782 as the surrogate)	1 minute
Poliovirus Type 1, Strain Brunhilde	(ATCC VR-1000)	1 minute
Rhinovirus Type 14	(ATCC VR-284)	1 minute
Rotavirus WA	(Acquired from University of Ottawa)	1 minute

**(Veterinary Viruses:)**

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

Avian Influenza A (H3N2)	(ATCC VR-2072)	1 minute
Feline Calicivirus, Strain F9	(ATCC VR-782)	1 minute
<b>TUBERCULOCIDAL:</b>		
[Note to reviewer: Only one of the following statements will be on the product label]		
(in the presence of 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)		
- or -		
(5 minute contact time)		
- or -		
(5 minutes)		
<b>(Organism)</b>	<b>(ATCC Number)</b>	<b>(Contact Time)</b>
<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	<i>Mycobacterium bovis</i> (Tb) (OT 451C150)	5 minutes
<b>FUNGICIDAL:</b>		
[Note to reviewer: Only one of the following statements will be on the product label]		
<i>Trichophyton interdigitale</i> (ATCC 9533) (formerly <i>Trichophyton mentagrophytes</i> ) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 minute contact time at 20°C (68°F) when used as directed on hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other clean, hard, non-porous, surfaces commonly contacted by bare feet.)		
- or -		
(This product is fungicidal against the pathogenic fungi, <i>Trichophyton interdigitale</i> (ATCC 9533) (formerly <i>Trichophyton mentagrophytes</i> ) (the fungus which causes Athlete's Foot) when used as directed on hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other clean, hard, non-porous, surfaces commonly contacted by bare feet.)		
- or -		
(This product is fungicidal against the pathogenic fungi, <i>Trichophyton interdigitale</i> (ATCC 9533) (formerly <i>Trichophyton mentagrophytes</i> ) (the fungus which causes Athlete's Foot) when used as directed on hard, non-porous surfaces.)		
- or -		
(in the presence of 5% serum load and 10 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)		
- or -		
(10 minute contact time)		
- or -		
(10 minutes)		
<b>(Organism)</b>	<b>(ATCC Number)</b>	<b>(Contact Time)</b>
<i>Trichophyton interdigitale</i> (ATCC 9533) (formerly <i>Trichophyton mentagrophytes</i> )	(ATCC 9533)	10 minutes
<b>Non-Food Contact Surface Sanitizer for hard non-porous surfaces:</b>		
[Note to reviewer: Only one of the following statements will be on the product label]		
(in the presence of 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.)		
- or -		
(in the presence of a 5% serum load and 30 second contact time (at 20°C (68°F)) on hard, non-porous environmental surfaces.)		
- or -		
(30 second contact time)		
- or -		
(30 seconds)		
<b>(Organism)</b>	<b>(ATCC Number)</b>	<b>(Contact Time)</b>
<i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE])	(ATCC 51575)	30 seconds
<i>Escherichia coli</i> O157:H7, (ATCC 35150)	(ATCC 35150)	30 seconds
<i>Klebsiella pneumoniae</i> , (ATCC 4352)	<i>Klebsiella pneumoniae</i> , (ATCC 4352)	30 seconds

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	<i>Pseudomonas aeruginosa</i> , (ATCC 15442)	30 seconds
<i>Salmonella enterica</i> , (formerly known as <i>Salmonella choleraesuis</i> )	<i>Salmonella enterica</i> , (ATCC 10708)	30 seconds
<i>Staphylococcus aureus</i> , (ATCC 6538)	<i>Staphylococcus aureus</i> , (ATCC 6538)	
<i>Staphylococcus aureus</i> , (ATCC 33592), (Resistant to Methicillin [MRSA])	<i>Staphylococcus aureus</i> , (ATCC 33592)	
<b>Soft Surface Spot Sanitizer</b> [Note to reviewer: Only one of the following statements will be on the product label]		
- (in the presence of 5% serum load and 30 second contact time on cotton or polyester fabrics (surfaces) - or - (30 second contact time) - or - (30 seconds)		
<b>(Organism)</b>	<b>(ATCC Number)</b>	<b>(Contact Time)</b>
<i>Staphylococcus aureus</i> ,	(ATCC 6538)	30 seconds
<i>Enterobacter aerogenes</i>	(ATCC 13048)	30 seconds
<i>Enterococcus faecalis</i> , (Resistant to Vancomycin [VRE])	(ATCC 51575)	30 seconds
<i>Staphylococcus aureus</i> , (Resistant to Methicillin [MRSA])	(ATCC 33592)	30 seconds
<i>Acinetobacter baumannii</i> , (Multi-Drug Resistant [MDR], Resistant to Cefazolin, Gentamicin, Trimethoprim/Sulfa, and Ertapenem)	(ATCC 19606)	30 seconds
<i>Klebsiella pneumoniae</i> , (Carbapenem-Resistant)	(ATCC BAA-1705)	30 seconds

<b>ALL SURFACES MUST REMAIN WET FOR:</b>
1 minute – Bacteria & Viruses
5 minutes – Tuberculosis
10 minutes - Fungi

**Malodor(s) (Activity) (Counteractancy)** – eliminates (destroys) odors and odor-causing bacteria on hard, nonporous surfaces in restroom areas, behind and under sinks and counters, and storage areas (and other places where bacterial growth can cause malodors).

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus.
- (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A<sub>2</sub> (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product has demonstrated effectiveness against Influenza Type A<sub>2</sub> (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

**(Emerging Pathogens Claims)**

(Oxivir Tb) (This product) meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
<b>Enveloped Viruses</b>	<ul style="list-style-type: none"> <li>• <b>Feline Calicivirus (ATCC VR-782) / Norovirus</b></li> <li>• <b>Rhinovirus Type 37 (ATCC VR-1147)</b></li> <li>• <b>Adenovirus Type 8 (ATCC VR-1368)</b></li> <li>• <b>Rotavirus, Strain WA</b></li> <li>• <b>Poliovirus type 1 (ATCC VR-1000), Strain Brunhilde</b></li> </ul>
<b>Large, Non-Enveloped Viruses</b>	<ul style="list-style-type: none"> <li>• <b>Feline Calicivirus (ATCC VR-782) / Norovirus</b></li> <li>• <b>Rhinovirus Type 37 (ATCC VR-1147)</b></li> <li>• <b>Poliovirus type 1 (ATCC VR-1000), Strain Brunhilde</b></li> </ul>
<b>Small, Non-Enveloped Viruses</b>	

(Oxivir Tb) (This product) has demonstrated effectiveness against viruses similar to *[insert name of emerging virus]* on hard, non-porous surfaces. Therefore, Oxivir Tb (this product) can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es) from list above]* on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at *[insert pathogen-specific website address]* for additional information.

*[Insert name of illness / outbreak]* is caused by *[insert name of emerging virus]*. Oxivir Tb kills similar viruses and therefore can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es)]* on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

**For Use as a Cleaner or One-Step Disinfectant Product:**

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. All surfaces must remain wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

Note: Rinsing is not necessary unless floors are to be coated with finish or restorer. All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

**For Use as a Tuberculocide:**

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain visibly wet for 5 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

**To Kill Fungi:**

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow surface to remain visibly wet for 10 minutes.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

**\*KILLS HIV AND HCV and HBV ON PRE-CLEANED INANIMATE SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 (AIDS Virus), HBV OR HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** (Disposable ) Protective Gloves (latex, nitrile, or vinyl gloves), gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**Cleaning Procedures:** Blood/Body Fluids must be thoroughly cleaned from surfaces/objects before application of this product.

**Contact Time:** Allow surface to remain visibly wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tb and a 10 minute contact for fungi.

**Disposal of Infectious Material:** Blood/Body Fluids must be autoclaved and disposed according to Federal, State and local regulations for infectious waste disposal.

**Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses):  
For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.**

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces by spraying with product for a period of 1 minute. Use a 5 minute contact time for TB and a 10 minute contact time for fungi.
5. Spray handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.
6. Ventilate buildings and other closed spaces.
7. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, mangers, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

**For Use to Clean and Disinfect Life Science Laboratory Surfaces:**

1. Pre-clean heavily soiled areas.
2. Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly.
3. Allow the surface to remain visibly wet for 1 minute. Use a 5 minute contact time for Tb and a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

**For use as a Non-Food Contact Sanitizer:**

1. Pre-clean heavily soiled areas.
2. Apply Solution with spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain visibly wet for 30 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

**To Spot Sanitize Soft Surfaces:**

1. Remove gross filth prior to sanitization.
2. Hold bottle upright 6 – 8" from surface. Spray until fabric is wet. DO NOT SATURATE.
3. Allow surface to remain visibly wet for 30 seconds.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

4. (Gently blot with a clean (damp) (color-safe) cloth) (and) (or) Let air dry. [For difficult odors or heavy fabrics, repeat application.] [Repeat as needed.]

[Note: Prior to first use on a particular surface, it is recommended to test in a small, discreet area if there is concern of incompatibility.]

**For Use as a Cleaner and/or Deodorizer:**

Spray evenly over hard, non-porous inanimate surface to be cleaned, 6 – 8 inches from surface, making sure to wet surfaces thoroughly. Wipe surfaces dry (or rinse) (or allow to air dry).

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal. Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE STORAGE**

Store in a dry, well-ventilated area away from chemicals, direct light, heat or open flame. Do not mix with other cleaning or disinfecting products.

**PESTICIDE DISPOSAL**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For more information on the disposal of unused, unwanted product and the clean up of spills, contact the EPA Regional Office of the Manufacturer for guidance.

**CONTAINER DISPOSAL** (Note to reviewer – One or more of the following paragraphs for Container Disposal will be selected, depending on packaging type:)

**NONREFILLABLE SEALED OR SMALL CONTAINERS:** (Note to reviewer: Several of our packaging options are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed, sonically welded, sealed containers. The following text will be used on these sealed container types or containers 5 gallons or smaller:)

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash (or offer for recycling if available).

**NONREFILLABLE NON-RIGID CONTAINERS:** Note to reviewer: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers (such as ACCUPACK™ Containers). These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

**LARGE NONREFILLABLE CONTAINERS:** Note to reviewer: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):

Nonrefillable container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer container for reconditioning, if appropriate.

OR

Nonrefillable container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)

use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

**REFILLABLE CONTAINERS:** *Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name) pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

**ENVIRONMENTAL HAZARDS** *(for labels with veterinary use patterns)*

This product is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk.

**ENVIRONMENTAL HAZARDS** *(for containers of 5 gallons or 50 lbs. or more)*

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.**

(Insert Emergency Number Here)

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

Optional Graphics:



EPA Reg. No. 70627-56  
EPA Est. No.  
(Lot code letters indicate establishmer

[Manufactured for:] © 2018 Diversey, I

U.S.A. All Rights Reserved.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer.)



AHP™ is a (registered) trademark of Virox Technologies Inc. used under license.

## **OXIVIR Tb REFERENCE SHEET**

*(Insert verbatim any Claims statements from the Claims sections from above.)*

### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

*(Insert verbatim any set(s) of Directions For Use from above)*

See the container label for use directions and additional required information for First Aid, Precautionary Statements, and Storage and Disposal.

EPA Reg. No. 70627-56

[Manufactured for:] © 2018 Diversey, Inc., P.O. Box 19747, Charlotte, NC 28219-0747 U.S.A. All Rights Reserved.